

# Exhibit 67-A

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## **The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the 1960's to the Early 2000's for Amphibole Asbestos**

### **Supplemental Report**



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## **The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the 1960's to the Early 2000's for Amphibole Asbestos**

### **Supplemental Report**

This supplemental report contains the following new analysis work by MAS:

1. ATEM and PLM analysis of 15 historical railroad car samples supplied by Imerys.
2. Additional Blount/PLM analysis of the 16 J<sup>3</sup> STS samples (15 separate STS containers) supplied by J&J.
3. Additional XRD analysis of the 10 MDL samples from project M69042, two MDL samples (one container) from M68233 and the seven MDL Asian samples (M69248) supplied by J&J.

### **Overview**

#### **Historical J&J Containers**

This supplemental report describes the procedures and methodology used by both MAS and J<sup>3</sup> Resources Inc. to analyze 71 separate historical containers and samples of Johnson & Johnson's (J&J) Baby Powder (JBP), Shower to Shower (STS) and Imerys' railroad car cosmetic talcum powder for the possible presence of amphibole asbestos. The J&J and Imerys' containers and samples analyzed for this report were all supplied by both J&J and Imerys from their historical inventory.

The 71 J&J and Imerys-supplied historical cosmetic talcum powder containers/samples analyzed for this report, were chosen from the 1960's, 1970's, 1980's, 1990's and early 2000's.

The 71 product sample set consisted of 56 JBP/STS containers, and 15 historical Imerys' samples that were described as "railroad car" samples. The source of the talcum powder for these historical JBP/STS and Imerys containers/samples came from both the Italian (1960's, JBP/STS) and Vermont (1960's, 1970's, 1980's, 1990's, early 2000) talc mines. Included in this report are seven Asian Historical JBP samples that MAS analyzed from possibly only from the 1980's. The source of the talc that J&J used for these historical Asian samples was from the Dongyang talc mine in Korea.



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Of the 56 Historical JBP/STS containers reported here, 34 were JBP and 22 were STS.

### **Historical Imerys Samples**

The additional 15 historical Imerys-supplied railroad car samples incorporated into this supplemental report were chosen from 1989, the 1990's and the early 2000's.

The addition of 15 Imerys' samples brings the total number of both historical containers (JBP/STS) and historical samples (Imerys) that MAS has now analyzed for the MDL to 71. This is in addition to the 35 JBP/STS containers (March 11, 2018 Supplemental Report) that were supplied by both plaintiffs' counsel and MAS.

This now would bring the total number of J&J/Imerys cosmetic talcum samples analyzed by MAS to 106.

### **J<sup>3</sup> and MAS' Analysis of Historical STS Samples**

Of the 56 historical JBP/STS talcum powder containers that were analyzed and reported here, 41 JBP/STS containers were analyzed by MAS and 15 STS containers (MAS verified by ATEM & PLM) were previously analyzed by Lee Poye of J<sup>3</sup> Resources Inc., located in Houston, Texas.

For the Lee Poye ATEM analysis, initially MAS was unable to verify the results of two J<sup>3</sup> ATEM STS sample analyses (20180061-63D and 20180061-10D). Both of these samples were reported to contain one asbestos anthophyllite structure in each. These two STS samples were not reported in our November 11, 2018 Supplemental Report since we could not verify if they were either positive or negative for amphibole asbestos.

Since the November 11, 2018 report, MAS has received the 16 STS samples (15 containers) from Lee Poye and has analyzed all of these samples by the PLM/Blount method. The two STS samples (20180061-63D and 20180061-10D) that MAS could not verify by ATEM, were positive for regulated amphibole by the Blount/PLM method.

The two STS containers positive for amphibole asbestos are now included into this supplemental report. Our November 11, 2018 expert report provided analysis of 54 historical J&J product containers, and with the addition of these two now verified (Lee Poye STS product containers 20180061-63D and 20180061-10D). This supplemental report is now providing the analytical results for 56 historical JBP/STS containers.

Also, when MAS analyzed five J<sup>3</sup> ATEM non-detect STS samples by the Blount/PLM method, four of these five ATEM non-detects were found to be positive for amphibole asbestos by the Blount/PLM method. The one remaining ATEM non-detect J<sup>3</sup> STS sample (20180061-02D), was found to be a non-detect for asbestos by the PLM/Blount method.

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As described in our November 11, 2018 report, MAS sent a number of the historical J&J samples to J<sup>3</sup> Resources for both PLM and XRD analysis using the ISO 22262-1 and ISO 22262-3 protocols. For this supplemental report, 17 additional historical J&J samples (M69042, M69248 and M68233) were sent to Lee Poye for XRD analysis using the ISO 22262-3 method.

### **Cosmetic Talc Analytical Methods**

The three principle analytical methods used by both J<sup>3</sup> and MAS for the analysis of the 56 J&J cosmetic talc containers were X-ray diffraction (XRD), polarized light microscopy (PLM) and analytical transmission electron microscopy (ATEM). For the 15 individual historical Imerys' railroad car samples, were only analyzed by the PLM and ATEM methods. The Imerys' railroad car samples were not analyzed by XRD. The reasons for this will be discussed later in this report.

The three analytical methods use the in this report all have strengths and weaknesses where it is expected, that amount of amphibole asbestos content would be at or below 0.1 wt. %.

### **XRD**

For cosmetic talc the XRD has the advantage of analyzing very large samples as compared to either PLM or ATEM. The disadvantages are 1) poor analytical sensitivity for bulk cosmetic talc samples when the potential amphibole asbestos concentration is typically below 0.1 to 0.3 weight % (wt.%), and 2) XRD cannot determine the crystalline habit (fibrous vs. non-fibrous) of amphibole minerals. However, for the majority these samples, XRD (ISO 22263-3) was used so that a comparison of the results to both PLM and ATEM analysis could be made in this report.

### **PLM**

The PLM method is primarily used today for the analysis of asbestos-added products where the asbestos-content of these products are typically over 1 % by weight.<sup>1,2,3</sup>

The strengths of the method are that it can positively identify the different regulated asbestos mineral types and provide a qualitative estimate of the weight percent of asbestos. The primary weaknesses of the method are 1) analytical sensitivity issues for samples that may contain less than 0.1 wt. % of asbestos such as cosmetic talcs and 2) because asbestos fiber and bundle structure resolution in the PLM method is dependent on the wave length of light,

<sup>1</sup> ISO 22262-1: 2012E Air Quality Bulk Materials Part 1: Sampling and Qualitative Determination of Asbestos in Commercial Bulk Samples.

<sup>2</sup> The Asbestos Particle Atlas, Dr. Walter C. McCrone, Director McCrone Research Institute, Ann Arbor Science, 1980.

<sup>3</sup> EPA/600/R-93/116.



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asbestos particles must be at least 0.5  $\mu\text{m}$  in the smallest dimension to be visible. Interesting enough, Dr. Walter McCrone stated: *"I have never seen rolled talc plates as fibers"* page 44, 3<sup>rd</sup> paragraph. For these analysis the ISO 22262-1 PLM method was used.

### **ATEM**

It is well recognized that the use of an analytical transmission electron microscope (ATEM) is the only analytical method with the appropriate sensitivity for the analysis of trace mineral concentrations that can be much less than 0.01 wt. %.

ATEM Strengths are: 1) it can positively identify potential fibrous chrysotile and amphibole asbestos structures by energy dispersive X-ray analysis (EDXA) for mineral fiber chemistry and crystalline structure information by selective area electron diffraction (SAED) and 2) The ATEM provides good morphology information that can, in most cases, distinguish between single fibers and bundles of regulated asbestos fibers.

The primary weakness for ATEM analyses of amphibole asbestos in cosmetic talcs is the sample preparation where overloading issues with the talc particles affects the analytical sensitivity of typical ATEM sample preparation procedures. Increasing analytical sensitivity usually involves the examination of hundreds of TEM grid openings and requires significant hours of TEM instrumentation time. Also, the ATEM is typically biased against detecting very large asbestos bundles that are routinely found by PLM.

### **Heavy Liquid Separation: PLM and ATEM Method**

The concern over analytical sensitivity for amphibole asbestos in cosmetic grade talc was first published in the peer-reviewed literature by A. M. Blount.<sup>4,5</sup> It was estimated by Dr. Blount that for every 1,000 amphibole particles present there would be approximately 1,000,000 talc particles. To overcome this problem the author described the use of a heavy liquid density separation method that reduced the number of talc particles as compared to the potential presence of amphibole asbestos thereby increasing analytical sensitivity for the PLM analysis of the talc samples.

In addition to increasing the analytical sensitivity of the PLM analysis for cosmetic grade talc using the heavy liquid separation method as published by Blount, the heavy liquid separation

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<sup>4</sup> A.M. Blount "Amphibole Content of Cosmetic and Pharmaceutical Talcs", Environ. Health Perspectives, Vol. 94, 1991, pp. 225-230.

<sup>5</sup> Process Mineralogy IX: The Minerals, Metals and Materials Society, 1990, A.M. Blount "Detection and Quantification of Asbestos and Other Trace Minerals in Powdered Industrial-Mineral Samples", pp. 557-570.

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method can also be used to substantially increase the analytical sensitivity of the ATEM analysis of cosmetic talc samples as described in the ISO 22262-2 bulk materials method.<sup>6</sup>

Reducing the amount of talc increases the sensitivity of the ATEM analysis and it also increases the amphibole sensitivity by the ATEM method. It would also increase the efficiency of the analyst by eliminating the need to examine hundreds of TEM grid openings to achieve reasonable analytical sensitivity.

References for the use of heavy liquid density separation of cosmetic talc during the sample preparation stage was described first by Dr. Fred Pooley in 1971, the Colorado School of Mines Research Institute in 1973 and by Windsor Minerals, Inc., Dartmouth College in 1974.<sup>7, 8, 9</sup>

## **Over All Summary of Results**

### **J&J and Imerys**

The 56 JBP/STS containers (including the 7 historical Asian JBP containers) and the 15 individual Imerys' railroad car samples gives a total of 71 historical containers/samples that were incorporated into this supplemental report.

A summary of these results are as follows;

1. The analysis of 34 historical JBP containers found that 25 were positive or 71 % positive.
2. The analysis of 22 historical STS containers found that 17 were positive or 77 % positive.
3. The analysis of 15 individual Imerys' railroad car samples found that 8 were positive or 53 % positive.

Excluding the seven JBP Asian historical containers would then give a total of 64 JBP/STS & Imerys' containers/railroad car samples analyzed; 43 were positive (67 %) for amphibole asbestos.

A summary of the results excluding the Asian JBP containers:

1. 28 historical JBP container analyses; 19 were positive or 68 % positive.

<sup>6</sup> ISO 22262-2: 2014E Air Quality-Bulk Materials Part 2: Quantitative Determination of Asbestos by Gravimetric and Microscopical Methods.

<sup>7</sup> March, 1974: to Windsor Minerals, Inc., Windsor, Vermont from R.C. Reynolds, Jr., Department of Earth Sciences, Dartmouth College, Hanover, New Hampshire: "Analysis of Talc Products and Ores for Asbestiform Amphiboles".

<sup>8</sup> Research and Engineering Center, August 11, 1971 Memo to File. FDA Meeting-Asbestos in Cosmetic Talc, August 3, 1971-Washington, D.C.

<sup>9</sup> Colorado School of Mines Research Institute "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers".



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2. 22 historical STS container analyses; 17 were positive or 77 % positive.
3. 15 individual Imerys' railroad car samples; 8 were positive or 53 % positive.

#### **XRD**

All 56 JBP/STS (Italian and Vermont talc mine source) talcum powder samples analyzed by XRD were found to be negative or non-detect by this method. Of the seven Asian JBP containers analyzed, two were positive and one sample was inconclusive. The 15 Imerys' railroad car samples were not analyzed XRD.

#### **PLM**

When 61 of the JBP/STS containers and Imerys samples were analyzed by MAS using PLM (ISO 22262-1) method (no heavy liquid density separation), 20 of the samples were positive for regulated amphibole asbestos or 33 % positive.

The Blount/PLM heavy density method found that out of the 71 JBP/STS and Imerys' containers/samples analyzed, 41, or 58 %, were positive for regulated amphibole asbestos.

For the ISO PLM method the amount of asbestos found for the positive samples were all <0.1 %. The Blount PLM method the amount of asbestos found ranged from <0.1 % to 0.7 %.

#### **ATEM**

The ISO 22262-2 ATEM (MAS and Lee Poye verified) analysis showed that in 69 JBP/STS and Imerys' railroad car talcum powder samples, 41, or 59 %, contained detectable amounts of amphibole asbestos fibers and bundles (tremolite solid solution series and or anthophyllite solid solution series). Neither chrysotile nor anthophyllite without iron was detected in any of the ATEM samples.

By ATEM, the amphibole asbestos concentration for the 41 positive JBP/STS and Imerys talcum powder samples ranged from between 4,370 fibers-bundles/gram to 268,000 fibers-bundles/gram of talcum powder.

All of analysis (PLM, Blount/PLM and ATEM), 50 (70 %) of the 71 container/samples were positive for regulated amphibole asbestos.

Two different regulated amphibole asbestos types were found. These were the tremolite asbestos solid solution series amphiboles which includes tremolite, winchite, richterite, and actinolite (only tremolite was detected by ATEM) and the anthophyllite asbestos solid solution



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series that includes anthophyllite, iron-rich anthophyllite, ferro-anthophyllite, cummingtonite and grunerite.

No anthophyllite asbestos (without iron) or chrysotile fibers/bundles were found in any of the 41 positive J&J talcum powder samples we analyzed by ATEM. A more detailed explanation for the lack of anthophyllite (without) iron or chrysotile fiber findings can be found in the Discussion and Conclusion Section of this report.

### **Fibrous Talc**

In addition to tremolite series and anthophyllite series amphibole asbestos, 42 of the 69 JBP/STS and Imerys' talcum powder samples analyzed by ATEM were observed to contain fibrous talc. A semi-quantitative calculation for the amount fibrous talc for each of the positive ATEM samples was also done. The concentration for each of the fiber talc positive ATEM samples ranged from 290,000 talc fibers per gram to 1,020,000 talc fibers per gram of product.

The 16 J<sup>3</sup> ATEM sample analysis did not provide enough information to perform a semi-quantitative fibrous talc calculation, and therefore, was reported as not applicable (NA).

The ISO 22262-1 PLM method found that for the 55 Italian and Vermont sourced talc samples analyzed, 54 (98 %) contained fibrous talc. The Blount/PLM method showed that of 71 samples analyzed, 20 (28 %) contained fibrous talc.

## **Materials and Methods**

### **Sample Log-In Procedure**

The JBP/STS and Imerys' talcum powder samples that were analyzed by MAS for this report were provided by both Johnson & Johnson and Imerys from their historical sample depository. The J&J historical samples were received by MAS in four separate sets and logged into MAS' sample tracking system and assigned to MAS project numbers as follows; **M68233**, two samples received at MAS on February 9, 2018. **M68503**, 75 samples received at MAS on March 29, 2018. **M69042**, 10 samples received at MAS on July 17, 2018 and **M69248**, seven Asian samples received at MAS on August 21, 2018. The Imerys historical samples were received by MAS in two separate sets and logged into MAS' sample tracking system and were assigned MAS project numbers as follows; **M69751**, 43 samples received at MAS on 12/7/2018 and **M69757**, 37 samples were received at MAS on 12/10/2018.

### **ISO-22262-1 and 3 PLM/XRD (J<sup>3</sup> Resources)**

On June 1, 2018, 75 J&J sample splits from M68503 and four spiked samples (tremolite and anthophyllite asbestos) were sent to Lee Poye for PLM and XRD analysis by ISO 22262-1 and 3.

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On November 28, 2018, 10 sample splits from M69042, seven sample splits from M69248 (Asian JBP Containers), and four spiked samples (tremolite and anthophyllite asbestos) were sent to Lee Poye for XRD analysis by ISO 22262-3. The results were provided to MAS from J<sup>3</sup> in a December 12, 2018 report and the data was added to this supplemental report.

On December 12, 2018, two sample splits from project M68233 were sent to Lee Poye for XRD analysis.

The results were provided to MAS from J<sup>3</sup> in a December 20, 2018 report and the data was added to this supplemental report.

#### **Muffle Furnace**

Approximately 1 to 2 grams (Sartorius Research Balance) of the 71 talcum powder was removed from each of the JBP/STS containers and Imerys samples and placed in a 15 ml glass scintillation vials. The scintillation vials were then placed in a Fisher Scientific Iso-temp muffle furnace Model #650 at 400°F for a minimum of 4 hours to remove any organic material.

#### **ISO-22262-1 PLM (MAS)**

Approximately 60 to 100 milligrams each of the 56 talcum powder samples were analyzed by the ISO 22262-1 PLM method. Three mounts of the talcum powder sample are placed on two glass slides, a drop of the 1.605 refractive index fluid was placed onto each of the three talcum powder mounts, stirred with the point of a scalpel blade, and then covered with an 18 x 18 mm glass cover slip. The entire area of the three coverslip mounts were examined (972 mm<sup>2</sup>). Positive identification of amphibole asbestos was done by morphology, refractive indices, elongation, angle of extinction, and birefringence. For positive samples, a visual estimation of the quantity of asbestos observed was based on eye calibration through review of lab generated weight percent standards. Visual calibration was augmented by the use of area percent charts.

#### **PLM/Blount Method**

Approximately 100 mg (Sartorius Research Balance) from each of the 71 JBP/STS and Imerys' muffled talcum powder sample aliquots were placed into individual labeled Eppendorf micro-centrifuge tubes (MCT) (Premium 1.5mL MCT Graduated Tubes Cat. No. 05-408-12).



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### **Density Separation**

Approximately 1.2 ml of Heavy Liquid (Lithium heteropolytungstates solution, GeoLiquids, Inc., Cat. No. LST010 with a stated density 2.85 g/cc diluted with distilled water to a density of 2.810 (determined by a VWR Hydrometer model number 34620-1109) was added to the MCT containing the 100 mg of the JBP/STS and Imerys' talcum powder samples and mixed with a disposable mixing rod for 10 to 20 seconds. The combined talc and LST heavy liquid (density 2.810 grams/cc) samples were placed into a vacuum desiccator (JEOL EMDSC-U10A) to remove air bubbles for 3 minutes at a pressure of approximately 8 Torr prior to centrifugation.

The MCT sample tubes were then placed in an Eppendorf micro-centrifuge (Model No. 5415D) set at 7,000 RPM for a total of 10 minutes at room temperature. After removal of the MCT tubes from the centrifuge, the talc/heavy liquid was pipetted off from the top of the centrifuge tube, distilled water was added, mixed and the sample was re-centrifuged as described above. This step was repeated two more times. After the third centrifugation/heavy liquid removal step, the heavy particles were removed from the bottom of the centrifuge tube with a pipette with several drops of water containing the heavy particles then transferred to a glass microscope slide and allowed to dry. The heavy particle residue on the glass slide was then analyzed by the ISO 22262-01 PLM method.

### **ATEM-ISO 22262-2 TEM Sample Preparation**

#### **Density Separation**

Approximately 20 to 30 mg (Sartorius Research Balance) from the muffled talc sample aliquot was placed into a labeled Eppendorf micro-centrifuge tube (MCT) (Premium 1.5mL MCT Graduated Tubes Cat. No. 05-408-12). Approximately 1.2 ml of Heavy Liquid (Lithium heteropolytungstates solution, GeoLiquids, Inc., Cat. No. LST010 density 2.85 g/cc) was added to the MCT containing the talc samples prepped and mixed with a disposable mixing rod for approximately 10 to 20 seconds. The combined talc and LST heavy liquid samples were then placed into a vacuum desiccator (JEOL EMDSC-U10A) to remove air bubbles for 15 minutes at a vacuum pressure of approximately 8 Torr prior to centrifugation.

The MCT sample tubes were then placed in an Eppendorf micro-centrifuge (Model No. 5415D) set at 9,000 RPM for total of 90 minutes at room temperature. After removal of the MCT tubes from the centrifuge, they were flash frozen in liquid nitrogen and the MCT tip was immediately removed with a pre-cleaned 6 inch steel cleaver into a clean 45 mL flat bottom disposable centrifuge tube. Figure 1 shows the cut area on the MCT tip.

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**Figure 1:**

**Cut Line for Removal of MCT Tip**



Red line is showing cut area on MCT tip

Deionized water was added to the centrifuge tube to bring the volume to approximately 45 ml. The 45 ml centrifuge tube was capped and inverted by hand 5 times to distribute the collected material in the bottom of the MCT tip. The 45 ml mixture was then immediately and continuously filtered onto a 25 mm Polycarbonate filter (PC) with a 22 $\mu$ m pore size. After the mixture was filtered, the excess heavy liquid was washed through the filter with the addition of approximately 100 ml of deionized water. The prepared PC filter was placed in a new disposable plastic 47mm petri dish and allowed to dry at ambient room temperature in a HEPA hood for a minimum of 2 hours. The processed PC filter samples were directly prepared onto TEM 100  $\mu$ m size grids (2 for analysis and 1 for archive) using either the standard TEM filter preparation protocol for MCE filters or for the PC filters.<sup>10, 11, 12, 13, 14, 13, 14</sup>

<sup>10</sup> D5755-09 "Standard Test Method for Microvacuum Sampling and Indirect Analysis of Dust by Transmission Electron Microscopy for Asbestos Structure Loading.

<sup>11</sup> D5756-02 "Standard Test Method for Microvacuum Sampling and Indirect Analysis of Dust Loading by Transmission Electron Microscopy for Asbestos Mass Surface.

<sup>12</sup> ISO 10312 1995-05-01, "Ambient Air Determination of Asbestos Fibers-Direct-Transfer Transmission Electron Microscopy Method.

<sup>13</sup> ISO 13794 1999 07-15, "Ambient Air-Determination of Asbestos Fibres-Indirect-Transfer Transmission Electron Microscopy Method.

<sup>14</sup> U.S. Environmental Protection Agency (USEPA) 1987. Asbestos Hazard Emergency Response Act, 40 CFR Part 763, Appendix A to Subpart E, USEPA, Washington D.C.



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### **ATEM Amphibole Analysis Procedure**

JEOL 1200EX ATEMs equipped with either a Noran or an Advanced Analysis Technologies (light element) energy dispersive x-ray analyzer (EDXA) were employed for this analysis. ATEM samples were analyzed at a screen magnification of 20,000X. Amphibole fibers or bundles with substantially parallel sides and an aspect ratio of 5:1 or greater, and at least 0.5µm in length were counted as regulated asbestos fibers and bundles per standard TEM counting rules as described by ASTM D5755, ASTM D5756, ISO 10312, ISO 13794, AHERA (TEM section only) and D7712-11.<sup>10,11,12,13,14,15</sup>

Positive identification of amphibole asbestos requires EDXA for mineral chemistry confirmation and selected area electron diffraction (SAED) for each amphibole type. At times, amphibole bundles may have a diameter that is too thick to acquire a SAED pattern, then, only the mineral chemistry can be used. For anthophyllite series asbestos, two separate angle SAED were acquired.

### **Counting Rules**

100 grid openings were analyzed for each of the JBP/STS and Imerys talcum powder samples. The 100 grid opening counts were split evenly between two grids.

All amphibole fibers/bundles that meet the above-stated size criteria were recorded on the MAS TEM structure count bench sheets for each sample. Length and width of each amphibole fiber/bundle was recorded and identified. Every amphibole structure identified and counted by the analyst required observation of an EDXA spectra matching the mineral chemistry for that particular amphibole and, if possible, a SAED amphibole pattern. EDXA spectra and SAED patterns (if an SAED pattern was possible) are recorded/saved for every asbestos amphibole structure found in the samples. Photomicrographs were taken of the amphibole fibers/bundles found from each of the samples that were positive for amphibole asbestos.

Results were reported as either amphibole asbestos fibers/bundles (structures) per gram of talc or in weight percent. Analytical sensitivity/detection limits were reported as structures per gram. The weight percent analytical sensitivity/detection limit was not provided in the November 11, 2018, since the procedure for calculating the detection limit is to use a theoretical mathematical calculation of one arbitrary minimal fiber dimension. Instead of an

<sup>15</sup> D7712-11 "Standard Terminology for Sampling and Analysis of Asbestos."

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arbitrary fiber dimension, a more accurate represented fiber size would be to use an average size for all the of detected amphibole fibers structures analyzed by ATEM in these samples. The average amphibole structure size was  $12.1\ \mu\text{m} \times 1.1\ \mu\text{m}$ , with an aspect ratio of 11:1. For this report, the more accurate weight detection limit was added to the data sets.

### **Fibrous Talc Estimation**

A number of the JBP/STS and Imerys talcum powder samples were found to contain fibrous talc during both types of the PLM analysis as well as the ATEM analysis. A quantitative analysis of the number of fibrous (asbestiform) talc particles was not done at this time. For the ATEM, a semi-quantitative estimate of the number of fibrous talc particles present in four random grid openings and observed throughout the 100 grid openings was scored as follows:

- 1) Abundant : (>11 fibrous talc particles)
- 2) Common: (4 to 10 fibrous talc particles)
- 3) Trace: (1 to 3 fibrous talc particles)

This estimation was based on the talc fibers/bundles having at least a 5:1 aspect ratio or greater, at least  $0.5\ \mu\text{m}$  in length and substantially parallel sides. One representative talc fiber or bundle was recorded (EDXA, SAED and photographed) for each of the samples that contained fibrous talc. Also, the finding of fibrous talc on random grid openings provided an overall estimate of how many talc fibers were on 100 grid openings analyzed for each of the samples.

For both PLM methods a visual estimation was made of the identified talc fibers and was reported as either trace or moderate (common).

### **Process Laboratory Blanks**

For each set of samples that were prepared by the heavy liquid method, one process laboratory blank was prepared with each set of samples. These process blank MCE filters were prepared in the same exact same manner as the talc samples (heavy liquid, filtration on MCE/PC filters, etc.) but without any talc material. For the TEM analysis, 100 grid openings were analyzed for each of the process blanks per sample set.



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## Results

### J<sup>3</sup> RESOURCES INC. ANALYSIS

#### **XRD ISO 22262-3 Method**

##### **J<sup>3</sup> Analysis**

Lee Poye of J<sup>3</sup> Resources analyzed 56 JBP/STS containers by the ISO 22262-3 XRD method. Of the 56 JBP/STS containers analyzed, 53 were non-detects, two were positive, and one was inconclusive by the XRD method.

For 49 JBP/STS containers where the source of the talc was either the Italian or Vermont mines, all were non-detects by XRD. The other seven were Asian historical JBP containers (the source of the talc was from the Korea mine) had two positive and one inconclusive and the other four samples were non-detects. The 15 Imerys railroad car samples were not analyzed by XRD.

A summary of all the XRD results are shown in Tables 7 & 8 to this report.

#### **PLM ISO 22262-1 Method**

##### **J<sup>3</sup> Analysis**

Using the ISO 22262-1 PLM method, J<sup>3</sup> Resources found that out of 38 samples analyzed, all were negative or non-detects. A summary of the J<sup>3</sup> results are also shown in Table 8 in this report.

#### **ATEM of Historical J&J Vermont Talc Shower to Shower Talcum Powder**

On July 18, 2018 Lee Poye of J<sup>3</sup> Resources, Inc. issued a report (to Joe Satterley of the Kazan Law Firm) of his analysis of 15 historical J&J Vermont talc Shower to Shower talcum powder samples that were split by J&J from their historical Shower to Shower (STS) containers that ranged in date from 1978 to 1986.<sup>16</sup>

Of the 15 STS containers (16 samples) analyzed by Lee Poye using the ISO 22262-2 heavy liquid TEM method, 11 of the 16 samples were positive for anthophyllite asbestos (solid solution series) and five samples were below the detection limit of the method. A summary of the 11 positive results are shown in Table 1.

<sup>16</sup> J3 Report for the Analysis of Shower to Shower Talc Samples, July 18, 2018.

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**Table 1**  
**J<sup>3</sup> TEM Results for Positive Vermont Talc Shower to Shower Samples**

Laboratory Control Number	J&J Sample Identification Number	STS Container Year	Mass Fraction Percent Wt.	Anthophyllite Asbestos (f/b) Concentration per g
20180070-07D	2014.001.0397	1978	$7.3 \times 10^{-4}$	82,370
20180061-37D	STS001	1982	$3.0 \times 10^{-5}$	9,257
20180061-38D	STS002	1980	$3.0 \times 10^{-3}$	53,416
20180061-45D	STS009	1982	$1.9 \times 10^{-3}$	9,000
20180061-52D	STS016	1980 - 1981	$4.0 \times 10^{-3}$	70,126
20180061-63D	STS027	1980	$3.5 \times 10^{-5}$	7,419
20180061-65D	STS029	1980 - 1981	$9.2 \times 10^{-3}$	95,321
20180061-10D	STS044	1980 - 1981	$2.6 \times 10^{-5}$	12,209
20180061-15D	STS049	1978	$1.3 \times 10^{-3}$	60,507
20180061-31F	STS065	1986	$2.9 \times 10^{-3}$	21,964
20180061-31G	STS065	1986	$5.2 \times 10^{-4}$	29,715

The above results were reported by J<sup>3</sup> as a mass fraction or weight percent. The calculations to the corresponding anthophyllite fiber/bundle concentrations per gram was done by MAS using the information provided on the J<sup>3</sup> TEM count sheets.

#### **Verification of Lee Poye's STS Results**

Lee Poye arrived at MAS on the morning of October 31, 2018 with one TEM grid box that contained the prepared TEM grids for J<sup>3</sup> project number JHI898969 for the J&J Vermont Talc STS samples. This information was confirmed by Lee Poye, that the TEM grids he brought to MAS was for the historical STS samples that he had previously analyzed.

In turn, MAS provided Mr. Poye with MAS TEM grid boxes for the 10 historical JBP talcum powder samples (MAS M69042). The MAS verification of the J<sup>3</sup> analysis was only for the 11 positive TEM sample analysis, the five sample results that were below the detection limit were not verified by MAS, and those results were accepted as true by MAS.

MAS was able to verify nine of the 11 ATEM positive historical STS talcum powder samples reported by J<sup>3</sup>. The nine positive MAS verified STS ATEM samples, two non-verified STS positive ATEM samples, and the five samples that were below the ATEM detection limit, were included in this overall report and are identified in summary Tables 3 and 4.



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A full report of the MAS verification analysis, verified count sheets, asbestos structure photo-micrographs, EDXA and SAED data is provided with this report.<sup>17</sup>

The overall summary of the results for the three analytical methods used for the 56 JBP/STS containers and 15 Imerys' historical railroad car samples analyzed for this report are summarized in Tables 2, 3, 4, 5, 6, 7, 8 and 9. These summary tables have been organized by decade from the 1960's (Table 2), 1970's (Table 3), 1980's (Table 4), 1990's (Table 5) early 2000's, (Table 6), Asian (Table 7), XRD and PLM (Table 8), and Fibrous (Table 9).

### **MAS ISO-22262-1 Analysis**

The ISO 22262-1 PLM analysis showed that out of the 46 JBP/STS containers and 15 Imerys' railroad car samples analyzed by MAS, 20 containers (30 %) had detectable amounts of regulated amphibole asbestos, the rest were either non-detects or contained actinolite/tremolite cleavage fragments that had an aspect ratio of < 3:1.

Results for all 20 positive samples were found to contain <0.1 % asbestos. Also, for these positive ISO PLM samples, both regulated actinolite/tremolite and or anthophyllite asbestos were found.

A summary of the MAS ISO 22262-1 PLM analysis results are shown in Tables 2, 3, 4, 5, 6 and 7 in this report.

### **Comparison of the J<sup>3</sup> ISO PLM to MAS ISO PLM Analysis for the Same Sample Set**

Both MAS and J<sup>3</sup> analyzed the same 22 J&J/STS talc samples by the ISO22262-1 PLM method. Where all 22 of the J<sup>3</sup> ISO PLM results were found to be negative, MAS found that 8 of the 22 were positive. A summary of this data is shown in Table 8.

### **PLM/Blount Method**

The Blount/PLM method showed that out of the 71 historical JBP/STS containers and Imerys' railroad car samples analyzed by MAS, 41 (58%) had detectable amounts of regulated amphibole asbestos and the rest were either non-detects or contained only tremolite/actinolite cleavage fragments that had an aspect ratio that was less than 3:1.

<sup>17</sup> Verification of Lee Poye's TEM Analysis of J&J's Historical Vermont Talc-Containing Shower to Shower Talcum Powder Samples, November 5, 2018.

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These 71 historical containers/samples analysis by the Blount/PLM also includes the 15 Lee Poye historical STS containers that were sent to MAS from J<sup>3</sup> on Nov 14, 2018 and received at MAS on Nov 16, 2018

Results for 41 positive samples were reported as an estimated weight percent range of from < 0.1% to 0.7 %. Also, for these positive Blount/PLM samples, both regulated actinolite/tremolite and or anthophyllite asbestos was detected.

The summary of the MAS Blount/PLM results are shown in Tables 2, 3, 4, 5, and 6 in this report.

#### **ATEM ISO 22262-2 Method**

The ISO 22262-2 ATEM heavy liquid separation method showed that out of the 69 historical JBP/STS containers and Imerys' railroad cars samples, 41 (59 %) contained regulated asbestos fibers and bundles. Two types of asbestos amphiboles were detected in these samples, they were either the tremolite asbestos solid solution series and or the anthophyllite solid solution series asbestos. Only the iron-rich anthophyllite asbestos was detected in the ATEM.

The amphibole asbestos structures per gram of talc ranged from below our analytical sensitivity/detection limit of approximately 4,200 - 9,000 fibers/bundles per gram to an amphibole asbestos concentration that ranged from 6,000 - 268,000 fibers-bundles/gram of talc. Also, for the positive ATEM samples the results were also expressed as a weight percent.

Tables 2 through 7 also provide the summary of ATEM findings for each of the 41 positive ATEM samples that were detected and the identification of the asbestos type for each of the measured amphibole asbestos fiber or bundles. This data includes length and width of the asbestos structure, individual fiber/bundle aspect ratios, and the average aspect ratio for each sample set.

All MAS and ISO PLM, Blount/PLM, ATEM analytical data, and photo-micrographs can be found in notebooks provided with this report that are labeled Historical 1960's, 1970's, 1980's, 1990's Early 2000's and Asian JBP/STS and Imerys' Analysis.

Each of these notebooks contain ISO PLM and Blount bench sheets and optical photo-micrographs for each sample. ATEM count sheets, EDXA spectra, SAED micrographs, and ATEM photo-micrographs for each of the regulated amphibole asbestos structures analyzed are included.

All the J<sup>3</sup> XRD and ISO PLM analyses are summarized in Tables 7 & 8. Also provided in Table 8 is a comparison of the J<sup>3</sup> ISO-PLM to the MAS ISO-PLM for the same sample analyses.



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### **Fibrous Talc JBP/STS Containers and Imerys Railroad Car Samples**

The MAS ISO 22262-1 PLM analysis showed that fibrous talc was found in 55 of 56 samples analyzed by this method and of the 71 samples analyzed by the Blount/PLM method, 28 of the samples were positive for fibrous talc.

The 57 MAS ISO 22262-1 PLM samples had concentrations of fibrous talc that ranged from trace to common (moderate) amounts.

For the MAS ISO 22262-2 ATEM analysis, 42 of the 69 (61 %) samples analyzed contained trace amounts of fibrous talc. The amount of fibrous talc per sample ranged from 290,000 talc fibers to 1,020,000 talc fibers per gram of cosmetic talcum powder.

No attempt was made to determine the amount of talc in 16 J<sup>3</sup> STS sample analysis ATEM bench sheets since it was unclear to us regarding the J<sup>3</sup> data collecting parameters and the amount of fibrous talc detected in the samples. This data is summarized in Table 9.

### **Process Blanks**

All of the process blanks that were run with each set of talcum powder samples were found to be negative for any asbestos fiber types. The ATEM bench sheets and summary are provide in a separate document supplied with this report.

### **Discussion**

#### **XRD ISO 22262-3**

All of the historical JBP/STS containers, where the source of the talc was either Italian or Vermont were found to be negative or non-detect by XRD. For the seven (7) Asian samples, two (2) of the samples were positive by the XRD analysis and one sample was inconclusive. The source of the talc that J&J used in these Asian products was from the Korean Dongyang talc mine in Korea. This talc mine has been characteristic in the past as an asbestiform tremolite asbestos talc mine. The documentation concerning the Dongyang mine Korea talc deposit and J&J's use of the talc from that has been produced to J&J in the *Leavitt* deposition.

The results show that the XRD method for either the Italian or Vermont cosmetic talc samples was inadequate to detect any tremolite or anthophyllite amphiboles at the concentrations found by the other analytical methods used (ISO PLM, Blount PLM and ATEM).

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For the Asian historical J&J cosmetic talc samples, two of the seven were positive for amphibole asbestos. When these same samples were analyzed by both the Blount/PLM and ATEM methods, six of seven samples were found to be positive for tremolite asbestos.

Based on these results there seems to be little value, even as a screening tool, to use XRD for cosmetic talcum powder samples when the source of talc is either from the Italian or Vermont mines. However, if the source of talc is from the Dongyang mine in Korea, there may be some limited value to use XRD as a preliminary screening tool for a tremolitic talc mine.

Since all 42 Vermont-sourced cosmetic talc samples were found to be negative for amphibole asbestos, there was no useful reason to analyze these additional 15 Imerys railroad car samples by XRD since the source of these Imerys cosmetic talc samples is from the same Vermont talc mines.

#### **MAS PLM-ISO 22262-1 Method**

The ISO PLM analysis performed by MAS detected 20 positives out of 61 samples that were analyzed. Many of the samples analyzed contained tremolite/actinolite cleavage fragments that had a typical aspect ratio of less than 3:1. No anthophyllite cleavage fragments were detected in any of the samples. For the positive samples, both regulated tremolite/actinolite and anthophyllite asbestos was detected at an estimated volume percent that ranged from <0.1 to 0.1 %.

All of the asbestos structures identified were large bundles that were typically greater than 50 microns long and 10 to 20 microns wide. No individual bundles were detected in any of these samples with widths less than 5 to 10 microns. However, individual fibers contained in these large bundles could be resolved with dispersive staining. The estimated average aspect ratio of the individual asbestos fibers in the bundles was greater than 20:1.

Lee Poye of J<sup>3</sup> Resources analyzed 22 historical JBP/STS by the ISO PLM that were provided by MAS and their 16 historical Vermont STS samples by this method. All 38 ISO PLM analysis were reported as non-detects.

When the same 22 historical JBP/STS samples were analyzed by MAS, 8 of the 22 samples were found to be positive.

These differing results between the two labs will require further investigation to understand the reason for these differences.



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### **Blount/PLM Method**

The Blount /PLM method heavy liquid separation method was able to increase the analytical sensitivity of the PLM analysis as compared to the ISO PLM method without heavy liquid separation. Of the 71 containers/samples analyzed by this method, 41 (59 %) were positive for regulated amphibole asbestos. For the positive samples, both regulated actinolite/tremolite and or anthophyllite asbestos were detected at a weight percent concentration for range of between <0.1% to 0.7 %. The estimated average aspect ratio of the individual asbestos fibers in the bundles was greater than 20:1.

When Dr. Blount published her heavy liquid separation PLM results in 1989/1990, one of the samples (sample I) was analyzed for tremolite asbestos. This sample was later determined to be a container of Johnson's Baby Powder.<sup>3, 4</sup> The source talc used by J&J, for their JBP product at that time (1989-1990), would have been from Vermont.

Our use of Blount PLM method, in particular for the Vermont sourced cosmetic talc samples, shows that Alice Blount was right and that her method increases the sensitivity of the PLM analysis for the detection of amphibole asbestos.

Dr. Blount published the use of the heavy liquid separation method in 1989/1990, however this was not a new technology for the analysis of cosmetic talc by PLM. Historical documents produced by J&J in this litigation shows that J&J was aware of the heavy liquid separation ("preconcentrating") of talc for the detection of asbestos in the early 1970s.<sup>8</sup> In 1973, a two part heavy liquid separations method report, for both chrysotile and tremolite-actinolite fibers, was done by the Colorado School of Mines on behalf of Johnson & Johnson.<sup>7</sup>

For this report, the Colorado School of Mines stated in their Summary and Conclusion section that the heavy liquid concentrates are examined by optical microscopy (PLM), and that "the procedure is capable of detecting fibers present at a level of approximately 10 ppm or less".<sup>8</sup> A 10 ppm (parts per million) detection limit calculates to a weight percent of 0.001 % which is consistent with our Blount PLM analysis of <0.1 % for positive samples.

In March of 1974, R.C. Reynolds Jr. wrote a report for Windsor Minerals Inc. entitled "Analysis of Talc Products and Ores for Asbestiform Amphiboles".<sup>9</sup> This method also used heavy liquid separation and PLM analysis. The purpose of the study was to "develop methods for measuring the concentration of asbestiform amphiboles in fine-grained talc products and talc ores". The report concluded that using this method detected 170 ppm (0.017 weight percent) of actinolite in a talc product and 2,300 ppm (0.23 weight percent) of actinolite in the talc ore.

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Even though Johnson & Johnson was aware from as early as 1973 that the heavy liquid separation PLM method increased the sensitivity for the detection asbestos in talc, they never incorporated this method for the routine analysis of their talc sources. Even when Dr. Blount published her heavy liquid separation PLM method in 1990, J&J still did not incorporate this more sensitive PLM method for the detection of asbestos in their cosmetic talc products.

It is clear from our data that the use of the Blount/PLM heavy liquid separation method increases the analytical sensitivity for the analysis of cosmetic talc samples like the JBP/STS products as compared to the ISO PLM method. Since some of the ISO 22262-1 PLMs were positive for the same samples that were non-detects by the Blount method, it's recommended that both PLM methods should be used to evaluating cosmetic talc samples for asbestos.

### **J<sup>3</sup> Resources, Inc.**

Our ATEM results for the historical JBP/STS samples are in agreement with the J<sup>3</sup> Resources, Inc. ATEM for the STS samples that they analyzed. For the nine J<sup>3</sup> samples that we verified from their TEM grids, J<sup>3</sup> also reported nine positive TEM samples and all contained regulated amphibole asbestos fibers/bundles. This correlates to 100 % agreement between the two labs for those nine samples.

For the 49 asbestos fibers and or bundles reported by J<sup>3</sup> in the 9 nine ATEM samples we examined, we verified 48 as regulated asbestos structures. This shows a 98 % validation rate between the labs. Additional analysis may in fact increase the overall verification percentage. Also, 90 % of the regulated anthophyllite asbestos structures were bundles.

The two J<sup>3</sup> ATEM samples (20180061-65D and 20180061-10D) that MAS did not verify, were verified to contained amphibole asbestos by the Blount PLM method. Even though we did not verify these two J<sup>3</sup> samples by ATEM, we did verify that these two J&J containers/samples were positive for regulated amphibole asbestos. For this reason, STS samples 20180061-65D and 20180061-10D were added to the overall list of positive 1980s historical J&J STS Vermont sourced talc containers.

### **ATEM-ISO 22262-2 Method**

The ISO 22262-2 heavy liquid talc preparation method for the direct ATEM analysis of approximately 20 to 30 mg of talc on a 25 mm PC filter did not cause any significant overloading of the TEM grids with talc particles. The overall TEM grid particle loading was estimated at approximately 15 to 20 %. This consisted of talc particles and/or fibers as well as detectible



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amphibole asbestos. The ATEM results showed that out of the 69 JBP/STS and Imerys samples analyzed by ATEM, both the MAS and Lee Poye's analyses, 41 were positive for either the tremolite solid solution series (tremolite, winchite, richterite and actinolite) in this case only tremolite was detected, and or the anthophyllite solid solution series (anthophyllite, iron-rich anthophyllite and cummingtonite) asbestos. Each of the tremolite or anthophyllite asbestos solid solution series amphibole mineral types are regulated asbestos.<sup>18</sup>

If the same weight of talc (approximately 20 to 30 mg) had been directly filtered onto a 25 mm PC filter, the TEM sample preparations would have been too severely overloaded with talc particles to be analyzed.

The heavy liquid density ATEM sample preparations demonstrated the utility of the ISO 22262-2 talc method by increasing the analytical sensitivity of the typical ATEM bulk talc analysis for the potential detection of amphibole asbestos. For these analyses the analytical ATEM achieved sensitivity/detection limits ranging from approximately 4,000 to 9,000 fibers-bundles/gram of talc. It also increased the analyst's efficiency without talc particle overloading issues.

This TEM talc loading problem vs. analytical sensitivity issued was been solved by the use of the heavy liquid density procedure, and should be the standard protocol for TEM cosmetic talc analysis.

As compared to either the XRD or the two PLM methods, the ATEM provides the most sensitive method for the detection of regulated amphibole asbestos in cosmetic talc.

#### **Numerical Structure Count vs. Weight Percent**

Our ATEM analysis showed that the asbestos fiber/bundle concentration, in the 41 positive samples ranged from approximately 4,000 to 268,000 fibers-bundles per gram of talcum powder. These positive results were also reported in weight percent that is based on a mathematical calculation. Also the analytical sensitivity or detection limit for the weight percent used here was based on the average size of all amphibole asbestos structures detected (187) in the 41 positive ATEM samples. This average size was determined to be 12.1  $\mu\text{m}$  x 1.1  $\mu\text{m}$ , with an aspect ratio of 11:1.

However, just reporting ATEM weight percent data does not provide any useful information for determining potential airborne exposure to asbestos structures of the bulk talc material being

<sup>18</sup> Current Intelligence Bulletin 62: "Asbestos Fibers and Other Elongated Mineral Particles". State of the Science and Roadmap for Research" Revised Edition. NIOSH CIB62-Asbestos.

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tested. The Introduction to the ISO 10312 Ambient Air TEM Method states the reasoning for this:

*"Because the best available medical evidence indicates that the numerical fibre concentration and the fibre sizes are the relevant parameters for evaluation of the inhalation hazards, a fibre counting technique is the only logical approach".*

Also, reporting the analytical sensitivity in weight by the ATEM method is very misleading since it is based on the theoretical mathematical calculation of one minimal fiber size which can give a computed analytical sensitivity in the millionths of a percent range. The misleading part of this is that in order to find that one small fiber during the ATEM analysis, you must have a real numerical fiber-bundle concentration per gram of talc for the analysis to possibly find that one fiber, otherwise this ATEM theoretical analytical sensitivity expressed in weight percent is meaningless.

An example of this problem can be found with the 2010 FDA report of the testing of cosmetic talcs that is published on their website. In that report, FDA states a TEM average limit of detection of 0.0000021 % wt. or  $2.1 \times 10^{6,19}$  However, when the ATEM analytical sensitivity was calculated from actual AMA TEM bench sheets, the numerical fiber concentration needed to find that one fiber was 13,500,000 fibers per/gram of talc.<sup>20</sup> A one fiber analytical sensitivity of that magnitude would have caused all of the ATEM analyses reported here to be non-detects.

### **Crystalline Habit an Asbestiform Definitions**

Each of the analytical protocols referenced in this report (PLM and TEM) all have a definition for asbestiform that is some variation of the following statement:

*Asbestiform: specific type of mineral fibrosity in which the fibers and fibrils possess high tensile strength and flexibility.*<sup>13</sup>

This definition of asbestiform in these protocols is only a general geological definition that might be used in the field to evaluate a particular commercial asbestos mine site, because the more fibrous, the greater economic value of the mine.

If this wasn't meant to be a general geological definition, then the methods would have incorporated into the counting protocols the procedures necessary for the determination or measurement of either the tensile strength or flexibility of the microscopic asbestos fibers and bundles. Of course, the methods do not measure flexibility or strength since that type of

<sup>19</sup> [www.FDA.gov](http://www.FDA.gov).

<sup>20</sup> AMA Analytical Services, Inc. Report of Cosmetic Grade Talc, 2010.



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measurement is impossible by either PLM or ATEM. None of these methods even define what high tensile strength is, or how many measurements constitute a population. Interesting enough, as compared to the commercial forms of asbestos (chrysotile, amosite and crocidolite), both tremolite and anthophyllite asbestos have low tensile strength and poor flexibility and yet are regulated asbestos fibers.<sup>21</sup>

Also, the vast majority of the fibrous amphibole asbestos structures reported here were bundles (as defined by parallel fibers in an asbestos structure that are closer than one fiber diameter to each other.

It is unreasonable to think that breaking up a non-fibrous asbestos can form multiple individual fibers all in close proximity and parallel to each other and that meets the definition of a bundle. That is why fibrous mineral bundles have been recognized in the published literature as asbestiform for many years.

In Blount's publication, she states the following:

*"In addition, the tendency to bring down a disproportional number of larger particles has the true asbestiform amphiboles one generally sees some particles showing bundles of fibrils which removes any doubt about the nature of the amphibole".<sup>5</sup>*

Dr. Wiley in her 1999 ASTM International publication stated that the finding of bundles shows that the structure should be considered asbestiform.<sup>22</sup>

The total amount of regulated asbestos structures counted in the 41 positive ATEM samples was 187 bundles and fibers. Asbestos bundles, as compared to fibers, was approximately 96 % of the regulated asbestos structures counted in the ATEM positive samples.

By definition, these asbestos bundles are all classified as asbestiform. Nevertheless, all fibers and bundles reported by the ATEM method are regulated asbestos structures regardless of the geological definition for asbestiform.

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<sup>21</sup> "Asbestos in Ontario, Ontario Department of Mines and Northern Affairs." Industrial Mineral Report 36, 1971.

<sup>22</sup> A.G. Wylie "The Habit of Asbestiform Amphiboles: Implications for the Analysis of Bulk Samples", ASTM Advances in Environmental Measurements Methods for Asbestos, STP 1342, Jan. 2000.

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For the single tremolite or anthophyllite fibers reported here, they all have been verified as to have formed in a fibrous crystalline habit since they are both fibrous and crystalline as well as meet the health based counting rules for regulated asbestos.<sup>23</sup>

### Aspect Ratio

Another aspect that must be considered is the milling process that is required to produce cosmetic grade talc and how it effects the overall asbestos size distribution and aspect ratios. This milling effects the asbestos size distribution in talcs was first discussed by Rohl, et al. in 1976.<sup>24</sup> In their publication the authors discuss how the talc milling process will break large fibers into a new size distribution in the submicroscopic range.

The average aspect ratio of the regulated asbestos tremolite and anthophyllite fibers and bundles measure by our ATEM analysis was approximately 11:1. This average aspect ratio was consistent to the Campbell data for milled tremolite and anthophyllite asbestos. Our measured average aspect ratios were also consistent with Blount's data for tremolite asbestos reported in sample I (identified as JBP).<sup>4, 25</sup>

This C5 tremolite asbestos structure aspect ratio is consistent with the NIST tremolite asbestos standard, Blount's tremolite asbestos findings for the off the shelf cosmetic talc container she tested, Campbell's milled tremolite asbestos and Langer & Nolan's published tremolite asbestos aspect ratio of 10.9 to 1. In the Blount publication, it was reported that the average aspect for non-asbestiform tremolite (cleavage fragments) was approximately 2:1.

Asbestiform tremolite/anthophyllite aspect ratio summary is as follows:

1. MDL ATEM analysis: : 11:1
2. Blount : 9:1
3. Campbell : 9:1
4. Langer : 11:1
5. J&J 3/11/2018 : 10:1
6. NIST 1875 Tre. Std. : 10:1

<sup>23</sup> Manual of Mineralogy, Twenty-First Edition, Revised, Cornelis Klein and Cornelis S. Hurlbert, Jr., John Wiley and Sons, 1999.

<sup>24</sup> Rohl, et al., "Consumer Talcum and Powders: Mineral and Chemical Characterization", Journal of Toxicology and Environmental Health, 2: pp. 255-284, 1976.

<sup>25</sup> Bureau of Mines Information Circular/Dept. of the Interior, Campbell, W.J., Blake, R.L., Brown, L.I., Cather, E.E. and Sjoberg, J.J.: United States Department of the Interior, "Selected Silicate Minerals and Their Asbestiform Varieties" IC 8751 1977.



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All of these independent laboratory tremolite asbestos aspect ratio data shows that the tremolite and anthophyllite structures detected by our ATEM analysis shows that they are in fact asbestiform.

As anticipated and discussed below, neither chrysotile nor non-iron containing anthophyllite asbestos was found in any of the samples that were analyzed by ISO 22262-02 ATEM analysis.

### **So Called Background Asbestos**

Of the 41 positive ATEM amphibole asbestos samples, nine of the JBP/STS talcum powder samples had only one amphibole asbestos fiber or bundle detected in 100 grid openings which represents the analytical sensitivity/limit of detection for this analysis.

Because tremolite/anthophyllite are non-commercial accessory amphibole minerals and are associated with talc, which is known to contain varying amounts of amphibole asbestos such as tremolite or anthophyllite, any positive findings are scientifically valid due to the amphibole minerals present in the talc.

There are no known commercial asbestos-containing products that used tremolite as an added ingredient, and only one specialty product ever used anthophyllite asbestos (corrosive resistant polymer chemical piping used at some chemical processing plants).

Further, there are no commercial amphibole tremolite/anthophyllite mines in North America, and tremolite and anthophyllite asbestos is not routinely analyzed at trace levels by typical commercial TEM laboratories. For these reasons it can be stated that: 1) there are no background air levels of tremolite/anthophyllite that could have interfered with or contaminated our JBP/STS and Imerys talcum sample analysis, and 2) for each set of JBP/STS and Imerys talcum samples that were prepared and analyzed at this laboratory a process laboratory blank was prepared simultaneously to determine if there was any possible cross-contamination.<sup>26,27</sup>

When these process laboratory blanks were analyzed by ATEM, no asbestos, including either tremolite, chrysotile or anthophyllite asbestos structures were found. Therefore, it can be stated that there was no cross-contamination during sample preparation of the JBP/STS talcum powder samples. Also, it is not our expectation that tremolite/anthophyllite asbestos would

<sup>26</sup> R.F. Dodson, M.F. O'Sullivan, D.R. Brooks and J.R. Bruce, "Asbestos Content of Omentum and Mesentery in Non-occupationally Exposed Individuals", *Toxicology and Industrial Health*, 2001: 17: pp. 138-143.

<sup>27</sup> R.J. Lee, D.R. Van Orden, "Airborne Asbestos in Buildings", *Regulatory Toxicology and Pharmacology*, 50 (2008) pp. 217-225.

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become a part of these homogenized talc products at a level identified as a matter of contamination prior to our custody of the samples. To do so would be practically impossible.

Also, these historical 71 JBP/STS containers and Imerys railroad samples came from their respective archived facilities. It is reasonable that the talcum powder in either the J&J containers or the Imerys railroad car samples were authentic and original to the specified date of manufacture (J&J containers) or time of product processing (Imerys). That is the talcum powder contained in these historical J&J container samples we analyzed, was the original talcum powder that was put into the container by J&J.

#### **Non-Detects**

For the 69 JBP/STS and Imerys talcum powder samples analyzed, ATEM results for 28 JBP/STS and Imerys talcum powder samples were less than the limit of detection of approximately 4,000 to 9,000 amphibole fibers/bundles per gram of talc. This result cannot be characterized to mean the samples do not contain amphibole asbestos. Rather, it can only be said that if there is any amphibole asbestos present, the fiber and bundles per gram of talc are at less than the detection limit for the ISO 22262-2 heavy liquid separation ATEM analysis.

#### **Chrysotile and Anthophyllite**

As anticipated, neither chrysotile nor non-iron containing anthophyllite asbestos was found in any of the 69 samples that were analyzed by the ISO 22262-02 ATEM analysis. However, iron-rich anthophyllite was detected by ATEM because of its increased density.

As with the ATEM method used here, the Blount PLM also uses heavy liquid separation in the sample preparation methodology.

The following is an explanation for the ATEM and Blount PLM chrysotile and anthophyllite results.

#### **ATEM Chrysotile Separation**

The ATEM heavy liquid method is specific for the asbestos tremolite solid solution series and the iron-rich anthophyllite solid solution series. The reason for this is that the heavy liquid solutions used for ATEM talc separation process had a density of 2.85 g/cm<sup>3</sup>. Therefore, any minerals with a similar density or lower would not be separated by this method such as



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chrysotile, which has a density of between 2.5 to 2.6 g/cm<sup>3</sup>.<sup>28</sup> The density for chrysotile is 0.020 g/cm<sup>3</sup> to 0.025 g/cm<sup>3</sup> less than the heavy liquid density used for the ATEM method and therefore, chrysotile asbestos would likely not be separated during JBP/STS and Imerys talcum sample preparation process.

As with the chrysotile non-detects reported here and in well over a hundred cosmetic talc analyses performed by MAS, the ATEM heavy liquid method has never detected chrysotile asbestos in the talcum powder, nor would we expect to have a positive result for chrysotile.

#### **ATEM Anthophyllite Solid Solution Series Separation**

The density of anthophyllite ranges from 2.85 to 3.20 g/cm<sup>3</sup>. This range of densities is primarily due to the addition of iron (Fe) into the chemical structure. For example, anthophyllite is part of a solid solution series (anthophyllite, iron-rich anthophyllite, ferro-anthophyllite, cummingtonite and grunerite) with a chemical formula of Mg<sub>7</sub>Si<sub>8</sub>O<sub>22</sub>(OH)<sub>2</sub> to approximately Fe<sub>7</sub>Mg<sub>5</sub>Si<sub>8</sub>O<sub>22</sub>(OH)<sub>2</sub>. Without Fe being present, the density of anthophyllite would be at the lower end of the density gradient of 2.85 g/cm<sup>3</sup>. Again, since anthophyllite is a solid solution series, the amount of iron atoms that can be substituted into the molecular formula of anthophyllite depends on the iron content of the surrounding rocks. This iron atom substituted could be 0, 1, 2 or higher which accounts for the range of anthophyllite densities described here.

With a low to non-iron anthophyllite density of approximately 2.85 to 2.86 or 2.87 g/cm<sup>3</sup>, which is the same or very close as the heavy liquid used for the ATEM analysis, one would not expect much separation of this type of either low-iron or non-iron containing anthophyllite from the talcum powders using the ISO 22262-2 ATEM method and typically would not be detected by our analysis if present.

As expected, all of the anthophyllite asbestos structures detected in these talcum powder samples by ATEM were iron-rich; no low iron or non-iron anthophyllite was detected in any of the ATEM samples. However, this does not mean actinolite/tremolite is not present in significant concentrations in the Vermont talc mines. The ISO 22262-2 and Blount/PLM analysis detected regulated actinolite/tremolite asbestos in 30 of the JBP/STS containers and Imerys railroad car samples. These results is further verification of the utility of using both PLM (with and without heavy liquid separation) and ATEM for analyzing cosmetic talc samples.

<sup>28</sup> Manual of Mineralogy, Twenty-First Edition, Revised, Cornelis Klein and Cornelis S. Hurlbert, Jr., John Wiley and Sons, 1999.

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### **Blount PLM Separation**

As described above, the ATEM detected only iron-rich anthophyllite asbestos primarily in the Vermont-sourced talcum powder samples which is consistent with the Blount PLM results. Comparing the type of asbestos detected (tremolite and anthophyllite) between the Blount PLM and ATEM analysis where the same sample is positive by both methods, the asbestos types found (either anthophyllite and or actinolite/tremolite) can be different between the two as already discussed in this report.

For example, the analysis for the historical JBP/STS and Imerys samples, showed a number of samples where the only type of asbestos detected by ATEM was the iron-rich anthophyllite, while the Blount PLM not only detected the anthophyllite but also detected actinolite/tremolite. This amphibole asbestos detection difference between the two methods may at times be a function of the different heavy liquid densities used for the Blount/PLM and ATEM protocols.

The Blount PLM protocol specifies a heavy liquid density of  $2.810 \text{ g/cm}^3$  as compared to the ISO 22262-2 ATEM method that uses a heavy liquid density of  $2.85 \text{ cm}^3$ . This difference of  $0.04 \text{ g/cm}^3$  is lower than the density of a low to non-iron anthophyllite. This lower density liquid used in the Blount PLM method would likely be more efficient in separating out the tremolite than the higher density liquid used by the ATEM method. Quite simply, the actinolite/tremolite structures would sink faster in the lower density liquid used by the Blount/PLM method. Also, the lower density liquid would be more efficient in separating out the low to non-iron anthophyllite asbestos.

This difference in the heavy liquid density between the two methods may explain why the number of positive Blount/PLMs for amphibole asbestos and the corresponding ATEM amphibole asbestos analysis were non-detect.

This density difference coupled with the ATEM's bias to the large amphibole asbestos bundles detected by the PLM method shows how important it is to use both of these methods when analyzing cosmetic talc samples.

These overall results are both consistent with and validates our earlier March 11, 2018 Supplemental JBP/STS Report and subsequent analysis of plaintiffs' personal JBP/STS containers.

However, for our testimony, we will only be relying on this report and any future supplemental reports involving the analysis of historical JBP/STS and Imerys containers and samples.



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These results are also consistent with MVA's analysis of talc ore samples from both the Italian and Vermont talc mines where originally the samples were collected by or on behalf of defendant experts.<sup>29, 30</sup>

Also, our analytical results are consistent with the historical analysis of both Johnson & Johnson's product samples as well as the analysis of talc ore from both the Italian and Vermont mines that have been performed in the past.<sup>31,32,33,34,35,36,37,38,39,40</sup>

In addition to the above references, we are also relying on the current MAS Johnson & Johnson reliance document list that contains 97 references.<sup>41</sup>

The ATEM and ISO PLM analysis also showed that the majority of the JBP/STS talcum powder samples contained fibrous (asbestiform) talc as compared to the platy talc that is present in all of JBP/STS and Imerys talcum powder samples. It has been reported by others that fibrous talc is a geological metamorphic transformation of anthophyllite to fibrous talc.<sup>42,43</sup>

## Conclusion

All Italian or Vermont talc sourced samples that were analyzed by XRD for asbestos were found to be negative or non-detect. These results show that the XRD method is not a useful tool at all for analyzing cosmetic talc samples (Italian or Vermont) for the presence of asbestos amphiboles. Both the ISO and Blount PLM methods have better analytical sensitivities than

<sup>29</sup> D.R. Veblen and C.W. Burnham, "New Biopyriboles Chester, Vermont: I. Descriptive Mineralogy", American Mineralogist, 63: 1000-1009, 1978.

<sup>30</sup> R.L. Virta, "The Phase Relationship of Talc and Amphiboles in a Fibrous Talc Sample, Bureau of Mines Report of Investigations 8923, United States Department of the Interior, 1985.

<sup>31</sup> November 26, 1990 McCrone Environmental Services Report to Michael J. Keener from Kent Sprague concerning Samples CWM 90-28, 9-29 and 90-30

<sup>32</sup> New Reagent Systems-Plant Trial at Windsor Minerals, Inc.

<sup>33</sup> March, 1974 Memo to: Windsor Minerals, Inc., Windsor, Vermont From R.C. Reynolds, Jr. Department of Earth Sciences, Dartmouth College, New Hampshire

<sup>34</sup> Forensic Analytical: Quantitative Analysis Report, Asbestos in Bulk Material.

<sup>35</sup> May 15, 1984 MSHA visit to Cyprus Industrial Minerals Company, South Plainfield Mill.

<sup>36</sup> Nov. 19, 1975 McCrone Assoc., Inc. Letter to Mr. Vernon Zeitz from Gene Grieger concerning talc ore sample analysis.

<sup>37</sup> Env. Consultant Report to Johnson & Johnson, April 1, 1977

<sup>38</sup> EMV Consultant Report to Johnson & Johnson, April 1, 1977

<sup>39</sup> Jan. 30, 1987 to J.A. Molnar and R.N. Miller from Joseph Schmidt Talc Analysis.

<sup>40</sup> March 14, 1988 to Mathew A. Nunes from Al Dickey, R.J. Lee Group Ref: Talc Samples 879-57 Talc L.

<sup>41</sup> Johnson & Johnson Reliance and Reviewed Documents (95).

<sup>42</sup> MVA Report: MVA11730 "Investigation of Italian Talc Samples for Asbestos", August 1, 2018.

<sup>43</sup> MVA Report: MVA12588 "Investigation of Talc Samples for Asbestos" April 23, 2018.

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XRD for these types of samples. It would be highly recommended that the Stimuli Group drop any consideration of using the XRD for their rewrite of USP 40 method.<sup>44</sup>

The use of the ISO 22262-1 PLM analysis was not as sensitive as the Blount PLM method, but both methods have their strengths and weakness. On one hand the Blount PLM method has higher sensitivity, but is limited by the type of anthophyllite it can detect. The ISO PLM has lower sensitivity, but can detect the entire anthophyllite solid solution series. Also, these two PLM methods can detect the very large bundles that are typically missed by the ATEM analysis. There are few examples where the sample was positive by PLM and negative by ATEM.

It is recommend then that both the ISO PLM and the Blount method should be used as a screening tool for cosmetic talc analysis. Negative samples should then be required to be analyzed by the heavy liquid density ATEM method, which is still the best tool for these types of analysis.

Our ATEM analysis showed that the Italian and Vermont talc mines have a very distinct asbestos type profile from each other when analyzed by this method. The historical samples from the Italian mine contained primarily regulated tremolite asbestos fibers/bundles while the Vermont mine contained primarily anthophyllite asbestos. However, for the MDL samples that contained Vermont sourced talc, the PLM results show that only six positive samples contained anthophyllite only, the rest of the positive PLM samples, for the two methods, had detectable amounts of regulated actinolite/tremolite asbestos. These results show that anthophyllite asbestos maybe more prevalent in Vermont talc, but significant concentrations of actinolite/tremolite asbestos is also present in the Vermont mines.

It is clear from these results that the three talc mines (Italian, Vermont and Korean) J&J used to manufacture their historical talcum powder products all contain asbestiform/regulated amphibole asbestos structures.

These overall results are both consistent and validates our earlier March 11, 2018 Supplemental JBP/STS Report and subsequent analysis of plaintiffs' personal JBP containers.

The most sensitive analytical method was ATEM with the ISO 22262-02 heavy liquid separation. It detected 41 positive samples out of the 69 JBP/STS and Imerys' talcum powder samples with a range in concentration of from 4,000 fibers-bundles/gram to 268,000 fibers-bundles/gram of talc. Both tremolite series and anthophyllite series asbestos were found in these samples.

<sup>44</sup> Stimuli to the Revision Process-Modernization of Asbestos Testing in USP Talc.



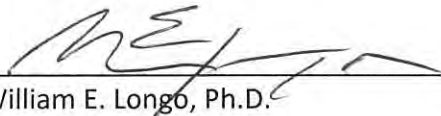
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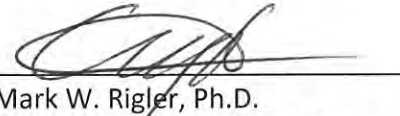


There was a total of 50 positive samples (ATEM and PLM combined) out of the 71 tested that gave an overall 70 % positive result for the historical JBP/STS containers and Imerys' railroad car samples that were tested for this report.

These results are also consistent with our past analysis of Johnson & Johnson cosmetic talc samples that contained tremolite and anthophyllite regulated asbestos fibers, and with MVA's analysis of both the Italian and Vermont talc mine ore samples.

Based on the results of our analysis, it is our opinion that individuals who used Johnson & Johnson talcum powder products (Johnson's Baby Powder and Shower to Shower) in the past would have, more likely than not, been exposed to significant airborne levels of both regulated amphibole asbestos and fibrous (asbestiform) talc.

  
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**Table 2**  
**Summary of Results for Johnson & Johnson's**  
**1960's Historical JBP & STS Samples**

MAS Sample Number	Client Sample ID	Year of Mnfr.	Amphibole Asbestos Structures/g	Amphibole Asbestos wt. %	Analytical Sensitivity Structures/g	ISO PLM wt. %	Blount PLM wt. %
M68503-010	2018-0060-04 JBP 167	1960	31,400	0.00056	8,500	NAD	<0.1 Trem/Act
M68503-009	2018-0060-03 JBP 166	1962	17,700	0.0000057	8,800	NAD	<0.1 Trem/Act
M68503-024	2018-0060-76 JBP 119	1963	<8,972	<0.0000268	9,000	NAD	NAD
M68503-004	2018-0056-25 JBP 232	1964	<2,990	<0.0000268	3,000	<0.1 Trem/Act	NAD
M68503-014	2018-0060-20 JBP 183	1965	17,300	0.000044	8,700	NAD	NAD
M68503-011	2018-0060-06 JBP 169	1966	<6,072	<0.0000268	6,100	NAD	NAD
M68503-027	2018-0061-09 STS 043	1966	<2,998	<0.0000268	3,000	NAD	NAD
M68503-019	2018-0060-44 JBP 087	1967	8,930	0.000045	8,900	NAD	NAD
M69042-003	20180056-31 JBP 238	1967	18,000	0.0000033	9,000	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act <0.1 Anth
M69042-005	20180060-25 JBP 188	1967	<8,740	<0.0000268	8,700	NAD	NAD
M69042-006	20180060-49 JBP 092	1967	<5,932	<0.0000268	5,900	NAD	NAD



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M69042-007	20180060-50 JBP 093	1967	<5,930	<0.0000268	5,900	NAD	NAD
M68503-038	2018-0061-40 STS 004	1968	<3,045	<0.0000268	3,050	NAD	NAD
M68503-026	2018-0061-08 STS 042	1969	268,000	0.0064	8,650	<0.1 Trem/Act	<0.1 Trem/Act

**M68503-010**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	7.0	0.7	10.0	Bundle	Tremolite
-2	12.0	0.9	13.3	Bundle	Tremolite
-3	20.0	3.5	5.7	Bundle	Tremolite
-4	3.7	0.5	7.4	Bundle	Tremolite

**Average Aspect Ratio: 9.1****M68503-009**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	3.8	0.72	5.3	Bundle	Tremolite
-2	3.5	0.42	8.3	Bundle	Tremolite

**Average Aspect Ratio: 6.8****M68503-014**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	8.6	1.3	6.6	Bundle	Tremolite
-2	7.9	0.84	9.4	Bundle	Tremolite

**Average Aspect Ratio: 8.0****M68503-019**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	20.0	1.0	20.0	Bundle	Anthophyllite

**Average Aspect Ratio: 20.0**

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**M69042-003**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	4.52	0.44	10.3	Bundle	Tremolite
-2	3.4	0.42	8.1	Bundle	Anthophyllite

**Average Aspect Ratio: 9.2**

**M68503-026**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	7.1	0.4	17.8	Bundle	Tremolite
-2	10.6	1.8	5.9	Bundle	Tremolite
-3	3.1	0.23	13.5	Fiber	Tremolite
-4	7.6	0.8	9.5	Bundle	Tremolite
-5	3.2	0.5	6.4	Bundle	Tremolite
-6	7.3	1.2	6.1	Bundle	Tremolite
-7	7.3	0.7	10.4	Bundle	Tremolite
-8	9.8	1.8	5.4	Bundle	Tremolite
-9	4.3	0.8	5.4	Bundle	Tremolite
-10	7.0	0.8	8.8	Bundle	Tremolite
-11	7.4	1.1	6.7	Bundle	Tremolite
-12	13.3	0.7	19.0	Bundle	Tremolite
13	3.7	0.45	8.2	Bundle	Tremolite
-14	3.4	0.6	5.7	Bundle	Tremolite
-15	3.2	0.23	13.9	Bundle	Tremolite
-16	30.8	4.0	7.7	Bundle	Tremolite
-17	2.8	0.5	5.6	Bundle	Tremolite
-18	7.9	0.92	8.6	Bundle	Tremolite
-19	7.5	0.8	9.4	Bundle	Tremolite
-20	3.9	0.6	6.5	Bundle	Tremolite
-21	4.1	0.6	6.8	Bundle	Tremolite
-22	3.0	0.46	6.5	Bundle	Tremolite
-23	24.4	3.0	8.1	Bundle	Tremolite
-24	6.5	1.1	5.9	Bundle	Tremolite
-25	8.6	0.92	9.3	Bundle	Tremolite
-26	27.6	3.7	7.5	Bundle	Tremolite



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-27	18.4	2.3	8.0	Bundle	Tremolite
-28	75.9	4.6	16.5	Bundle	Tremolite
-29	9.2	1.4	6.6	Bundle	Tremolite
-30	4.6	0.7	6.6	Bundle	Tremolite
-31	6.9	1.0	6.9	Bundle	Tremolite

**Average Aspect Ratio: 8.7**

**Table 3**  
**Summary of Results for Johnson & Johnson's**  
**1970's Historical JBP & STS Samples**

MAS/J <sup>3</sup> Sample Number	Client Sample ID	Year of Mnfr.	Amphibole Asbestos Structures/g	Amphibole Asbestos wt. %	Analytical Sensitivity Structures/g	ISO PLM wt. %	Blount PLM wt. %
M68503-005	2018-0056-30 JBP 237	1970	<8,778	<0.0000268	8,780	NAD	NAD
M69042-009	20180060-68 JBP 111	1970	<6,371	<0.0000268	6,370	<0.1 Trem/Act	NAD
M68503-029	2018-0061-17 STS 051	1971	<8,417	<0.0000268	8,400	NAD	NAD
M68503-021	2018-0060-54 JBP 097	1972	<5,918	<0.0000268	5,920	NAD	NAD
M68503-023	2018-0060-64 JBP107	1973	8,760	0.000017	8,730	<0.1 Anth	<0.1 Anth
M68503-028	2018-0061-12 STS 046	1974	17,500	0.000098	5,800	NAD	<0.1 Anth
02D	20180061-02D STS 1611A	1975	<9,400	<0.0000268	9,400	P <sup>3</sup> -NAD	NAD
M69042-001	20180056-02D JBP 209	1975	22,400	0.000232	4,470	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act
M68503-046	2018-0061-57 STS 021	1975	<5,863	<0.0000268	5,900	NAD	NAD

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M68503-042	2018-0061-49 STS 013	1976	23,600	0.0024	5,890	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act
M68233-001	2018-0015-01A1 JBP	1978	7,240	0.00001	7,240	<0.1 Trem/Act	<0.1 Trem/Act
M68233-002	2018-0015-01A2 JBP	1978	22,130	0.00023	7,400	<0.1 Trem/Act	<0.1 Anth
M68503-057	2018-0070-10 2014.001.0612 JBP	1977	8,360	0.000038	8,360	<0.1 Trem/Act <0.1 Anth	NAD
M68503-020	2018-0060-53 JBP 096	1978	34,800	0.000053	8,690	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act
M69042-002	20180056-06 JBP 213	1978	63,800	0.00048	9,120	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act <0.1 Anth
M69042-004	20180056-34 JBP 241	1978	18,000	0.000012	6,020	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act <0.1 Anth
M69042-008	20180060-67 JBP 110	1978	18,100	0.00086	6,020	<0.1 Anth	<0.1 Anth
07D	20180070-07D 2014.001.0397	1978	82,000	0.00073	9,100	J <sup>3</sup> -NAD	0.2 Trem/Act 0.5 Anth
15D	20180061-15D STS049	1978	61,000	0.0013	8,700	J <sup>3</sup> -NAD	0.3 Anth
50D	20180061-50D STS 1605A	1978	<9,300	<0.0000268	9,300	J <sup>3</sup> -NAD	<0.1 Anth
M68503-059	2018-0070-16 JBP 2014.001.1363	1979	17,100	0.00024	8,560	<0.1 Trem/Act <0.1 Anth	<0.1 Trem/Act <0.1 Anth

NAD: No asbestos detected J<sup>3</sup>NAD: Samples analyzed by Lee Poye

#### M68503-023

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	12.0	0.8	15.0	Bundle	Anthophyllite

**Average Aspect Ratio: 10.7**



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**M68503-028**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	18.8	1.8	10.4	Bundle	Anthophyllite
-2	5.7	0.4	14.3	Bundle	Anthophyllite
-3	6.0	0.9	6.7	Bundle	Anthophyllite

**Average Aspect Ratio: 10.5**

**M69042-001**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	14.4	0.4	36.0	Fiber	Anthophyllite
-2	2.3	0.4	5.8	Fiber	Anthophyllite
-3	15.7	2.0	7.9	Bundle	Anthophyllite
-4	10.0	0.2	50	Fiber	Anthophyllite
-5	22.5	2.5	9	Bundle	Anthophyllite

**Average Aspect Ratio: 21.7**

**M68503-042**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	19.0	2.0	9.5	Bundle	Anthophyllite
-2	29.0	2.0	14.5	Bundle	Anthophyllite
-3	6.7	0.8	8.4	Bundle	Anthophyllite
-4	40.0	6.0	6.7	Bundle	Anthophyllite

**Average Aspect Ratio: 9.8**

**M68233-001**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	6.8	0.9	7.6	Fiber	Anthophyllite

**Average Aspect Ratio: 7.6**

**M68233-002**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	27.7	0.7	36.7	Bundle	Anthophyllite
-2	16.4	2.6	6.3	Bundle	Anthophyllite
-3	7.6	0.5	15.2	Fiber	Anthophyllite

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**Average Aspect Ratio: 19.4**

**M68503-057**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	8.0	1.5	5.3	Bundle	Tremolite

**Average Aspect Ratio: 5.3**

**M68503-020**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	8.5	0.42	20.2	Bundle	Anthophyllite
-2	2.7	0.44	6.1	Bundle	Tremolite
-3	4.62	0.62	7.5	Bundle	Anthophyllite
-4	21.1	0.98	21.5	Bundle	Anthophyllite

**Average Aspect Ratio: 13.8**

**M69042-002**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	35.4	1.8	19.7	Bundle	Anthophyllite
-2	12.4	1.1	11.3	Bundle	Anthophyllite
-3	6.4	1.1	5.8	Bundle	Anthophyllite
-4	6.0	0.7	8.6	Bundle	Anthophyllite
-5	34.5	1.1	31.4	Bundle	Anthophyllite
-6	11.5	1.2	9.6	Bundle	Anthophyllite
-7	11.5	1.0	11.5	Bundle	Anthophyllite

**Average Aspect Ratio: 14.0**

**M69042-004**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	13.4	0.4	33.5	Fiber	Anthophyllite
-2	4.2	0.38	11.1	Bundle	Anthophyllite
-3	13.4	0.63	21.3	Bundle	Anthophyllite

**Average Aspect Ratio: 21.9**



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**M69042-008**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	3.9	0.5	7.8	Bundle	Anthophyllite
-2	7.8	1.5	5.2	Bundle	Anthophyllite
-3	5.3	0.5	10.6	Bundle	Anthophyllite

**Average Aspect Ratio: 7.9**

**07D**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	3.5	0.25	14	Fiber	Anthophyllite
-2	6.0	0.4	15	Bundle	Anthophyllite
-3	7.5	0.2	37.5	Bundle	Anthophyllite
-4	11.0	0.6	18.3	Bundle	Anthophyllite
-5	4.0	0.25	16	Bundle	Anthophyllite
-6	14.0	1.1	12.7	Bundle	Anthophyllite
-7	8.5	0.4	21.3	Bundle	Anthophyllite
-8	9.0	0.7	12.9	Bundle	Anthophyllite

**Average Aspect Ratio: 18.5**

**15D**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	6.6	0.7	9.4	Bundle	Anthophyllite
-2	5.2	0.22	23.6	Bundle	Anthophyllite
-3	20.3	0.92	22.1	Bundle	Anthophyllite
-4	27.0	1.5	18	Bundle	Anthophyllite
-5	5.9	0.22	26.8	Fiber	Anthophyllite

**Average Aspect Ratio: 20.0**

**M68503-059**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	12.0	0.4	30.0	Bundle	Anthophyllite
-2	17.0	2.5	6.8	Bundle	Anthophyllite

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**Average Aspect Ratio: 18.4**

**Table 4**

**Summary of Results for Johnson & Johnson's  
 1980's Historical JBP & STS Samples**

MAS/J <sup>3</sup> Sample Number	Client Sample ID	Year of Mnfr.	Amphibole Asbestos Structures/g	Amphibole Asbestos wt. %	Analytical Sensitivity Structures/g	ISO PLM wt. %	Blount PLM wt. %
10D	20180061-10D STS 044	1980	N/A	N/A	N/A	J <sup>3</sup> -NAD	0.2 Tre/Act <0.1 Anth
38D	20180061-38D STS 002	1980	53,000	0.003	7,600	J <sup>3</sup> -NAD	0.2 Tre/Act 0.2 Anth
63D	20180061-63D STS 027D	1980- 1981	N/A	N/A	N/A	J <sup>3</sup> -NAD	0.2 Tre/Act 0.2 Anth
52D	20180061-52D STS 016	1981	70,000	0.004	7,800	J <sup>3</sup> -NAD	0.2 Tre/Act 0.5 Anth
65D	20180061-65D STS 029	1981	95,000	0.0092	7,300	J <sup>3</sup> -NAD	0.2 Tre/Act 0.2 Anth
37D	20180061-37D STS 001	1982	9,300	0.00005	9,300	J <sup>3</sup> -NAD	<0.1 Tre/Act <0.1 Anth
45D	20180061-45D STS 009	1982	9,000	0.0019	9,000	J <sup>3</sup> -NAD	<0.1 Tre/Act
51D	20180061-51D STS 1606A	1982	<9,400	N/A	9,400	J <sup>3</sup> -NAD	<0.1 Tre/Act
66D	20180061-66D STS 1610A	1982	<9,400	N/A	9,400	J <sup>3</sup> -NAD	0.1 Tre/Act
21D	20180061-21D STS 1614A	1983	<8,300	N/A	8,300	J <sup>3</sup> -NAD	<0.1 Tre/Act <0.1 Anth
M68503- 001	2018-0051-34 JBP 294	1984	18,700	0.000036	6,240	<0.1Tre/Act	<0.1 Tre/Act



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M69042-010	2018-0070-86 2014.001.5102 JBP	1985	12,500	0.000035	6,200	<0.1Tre/Act	<0.1 Anth
31F	20180061-31F STS 065	1986	22,000	0.0029	7,300	J <sup>3</sup> -NAD	0.3 Tre/Act < 0.1 Anth
31G	20180061-31G STS 065	1986	30,000	0.00052	7,500	J <sup>3</sup> -NAD	<0.7 Tre/Act
M69751-037	20180314-03 Imerys	1989	59,000	0.000089	4500	<0.1 Tre/Act	<0.7 Tre/Act

NAD: no asbestos detected. J<sup>3</sup>-NAD: Samples analyzed by Lee Poye. |

### 38D

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	3.2	0.6	5.3	Bundle	Anthophyllite
-2	3.6	0.7	5.1	Bundle	Anthophyllite
-3	18.9	1.5	12.6	Bundle	Anthophyllite
-4	6.0	0.9	6.7	Bundle	Anthophyllite
-5	6.2	1.1	5.6	Bundle	Anthophyllite
-6	3.5	0.4	8.9	Fiber	Anthophyllite
-7	6.0	0.3	20.0	Bundle	Anthophyllite
-8	3.1	0.25	12.4	Bundle	Anthophyllite

**Average Aspect Ratio: 9.6**

### 52D

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	46.5	1.5	31	Bundle	Anthophyllite
-2	29.2	1.5	19.5	Bundle	Anthophyllite
-3	10.0	0.5	20	Bundle	Anthophyllite
-4	22.5	1.3	17.3	Bundle	Anthophyllite
-5	11.7	1.0	11.7	Bundle	Anthophyllite
-6	9.5	1.0	N/A	Bundle	Talc
-7	31.0	1.0	31	Bundle	Anthophyllite
-8	9.0	0.25	36	Fiber	Anthophyllite
-9	3.8	0.3	12.7	Bundle	Anthophyllite

**Average Aspect Ratio: 22.4**

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**65D**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	18.0	1.5	12	Bundle	Anthophyllite
-2	14.3	1.5	9.5	Bundle	Anthophyllite
-3	20.2	1.3	15.5	Bundle	Anthophyllite
-4	11.2	0.7	16	Bundle	Anthophyllite
-5	6.8	0.7	9.7	Bundle	Anthophyllite
-6	13.3	0.7	19	Bundle	Anthophyllite
-7	22.3	1.5	14.9	Bundle	Anthophyllite
-8	17.0	0.22	77.3	Fiber	Anthophyllite
-9	28.0	2.5	11.2	Bundle	Anthophyllite
-10	9.5	1.3	7.3	Bundle	Anthophyllite
-11	12.0	0.8	15	Bundle	Anthophyllite
-12	10.2	0.4	25.5	Bundle	Anthophyllite
-13	23.0	3.5	6.6	Bundle	Anthophyllite

**Average Aspect Ratio: 18.4**

**37D**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	15.8	2.6	6.1	Bundle	Anthophyllite

**Average Aspect Ratio: 6.1**

**45D**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	17.5	2.2	8.0	Bundle	Anthophyllite

**Average Aspect Ratio: 8.0**



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**M68503-001**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	9.89	0.46	21.5	Bundle	Anthophyllite
-2	3.2	0.59	5.4	Bundle	Tremolite
-3	10.4	1.38	7.5	Bundle	Tremolite

**Average Aspect Ratio: 11.5**

**M69042-010**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	9.2	1.5	6.1	Bundle	Anthophyllite
-2	8.9	0.42	21.2	Bundle	Anthophyllite

**Average Aspect Ratio: 11.5**

**31F**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	21.6	1.3	16.6	Bundle	Anthophyllite

**Average Aspect Ratio: 16.6**

**31G**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	30.1	0.7	43	Bundle	Anthophyllite
-2	13.5	0.7	19.3	Bundle	Anthophyllite
-3	7.0	0.7	10	Bundle	Anthophyllite
-4	22.5	1.5	15	Bundle	Anthophyllite

**Average Aspect Ratio: 21.8**

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**Table 5**  
**Summary of Results for Johnson & Johnson's**  
**1990's Historical JBP & STS Samples**

MAS/J <sup>3</sup> Sample Number	Client Sample ID	Year of Mnfr.	Amphibole Asbestos Structures/g	Amphibole Asbestos wt. %	Analytical Sensitivity Structures/g	ISO PLM wt. %	Blount PLM wt. %
M69757-005	20180343-03A	1990	27000	0.000010	4500	<0.1 Tre/Act <0.1 Anth	<0.1 Tre/Act <0.1 Anth
M69757-007	20180358-01A	1990	39000	0.00030	4300	<0.1 Tre/Act	<0.1 Tre/Act <0.1 Anth
M69751-039	20180320-01A	1991	<4400	<0.0000268	4400	NAD	NAD
M69751-040	20180320-13A	1991	13000	0.000015	4500	NAD	<0.1 Tre/Act
M68503-016	2018-0060-33 JBP 001	1994	<9000	<0.0000268	9000	NAD	NAD
M69757-004	20180339-05A	1994	<4400	<0.0000268	<4400	NAD	NAD
M69751-036	20180313-02A	1995	4400	0.00000022	4400	NAD	NAD
M68503-017	2018-0060-38 JBP006	1996	<9000	<0.0000268	9000	NAD	NAD
M69757-006	20180344-04A	1996	<4400	<0.0000268	4400	NAD	NAD
M69751-002	20180315-021A	1999	<4400	<0.0000268	4400	NAD	NAD

NAD: no asbestos detected.



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**M69757-005**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	2.32	0.21	11.0	Bundle	Anthophyllite
-2	6.1	0.42	14.5	Bundle	Anthophyllite
-3	4.4	0.84	5.2	Bundle	Anthophyllite
-4	2.72	0.42	6.5	Bundle	Anthophyllite
-5	8.7	0.38	22.9	Bundle	Anthophyllite
-6	4.82	0.76	6.3	Bundle	Anthophyllite

**Average Aspect Ratio: 11.1**

**M69757-007**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	5.6	1.1	5.1	Bundle	Anthophyllite
-2	4.6	0.64	7.2	Bundle	Anthophyllite
-3	9.9	0.36	27.5	Fiber	Anthophyllite
-4	10.9	0.35	31.1	Bundle	Anthophyllite
-5	11.7	1.4	8.4	Bundle	Anthophyllite
-6	11.6	1.1	10.5	Bundle	Actinolite
-7	11.8	1.6	7.4	Bundle	Anthophyllite
-8	8	1.3	6.2	Bundle	Anthophyllite
-9	49.4	2.1	23.5	Bundle	Talc-Antho

**Average Aspect Ratio: 11.1**

**M69757-040**

Str. #	Length (μm)	Width (μm)	Aspect Ratio	Structure Type	Asbestos Type
-1	7.4	0.62	11.9	Bundle	Anthophyllite
-2	14.9	0.74	20.1	Bundle	Anthophyllite
-3	6.72	0.62	10.8	Bundle	Anthophyllite

**Average Aspect Ratio: 11.1**

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**M69757-036**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	6.3	0.18	35.0	Bundle	Tremolite

**Average Aspect Ratio: 35.0**

**Table 6**  
**Summary of Results for Johnson & Johnson's**  
**2000's Historical JBP & STS Samples**

MAS/J <sup>3</sup> Sample Number	Client Sample ID	Year of Mnfr.	Amphibole Asbestos Structures/g	Amphibole Asbestos wt. %	Analytical Sensitivity Structures/g	ISO PLM wt. %	Blount PLM wt. %
M69751-001	2018-0315-01A	2000	4400	0.000017	4400	NAD	NAD
M69751-006	2018-0316-020A	2000	4600	0.0000024	4600	NAD	<0.1 Tre/Act
M69751-007	2018-0316-021A	2000	8700	0.000024	4300	NAD	NAD
M69751-038	2018-0317-04A	2000	<4400	<0.0000268	4400	NAD	NAD
M69751-004	2018-0315-040A	2001	<4300	<0.0000268	4300	NAD	NAD
M69751-008	2018-0316-022A	2003	<4400	<0.0000268	4400	NAD	NAD

NAD: no asbestos detected.

**M69751-001**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	10.5	1.2	8.8	Bundle	Tremolite

**Average Aspect Ratio: 8.8**



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**M69751-006**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	8.2	0.5	16.4	Bundle	Tremolite

**Average Aspect Ratio: 35.0****M69751-007**

Str. #	Length (µm)	Width (µm)	Aspect Ratio	Structure Type	Asbestos Type
-1	16.0	1	16.0	Bundle	Tremolite
-2	7.6	0.9	8.4	Bundle	Tremolite

**Average Aspect Ratio: 12.2**

**Table 7**  
**Summary of J<sup>3</sup> XRD & PLM Analysis**  
**Asian**

MAS Sample Number	Date of Manuf.	ISO XRD
M69248-001	N/A	NAD
M69248-002	1979	inconclusive
M69248-003	1980-1984	positive
M69248-004	N/A	NAD
M69248-005	N/A	NAD
M69248-006	1982	NAD
M69248-007	N/A	positive

NAD: no asbestos detected N/A: dates of manufacture not provided by J&amp;J

**Table 8**  
**Summary of J<sup>3</sup> XRD & PLM Analysis**  
**1960's**

MAS Sample Number	Date of Manuf.	ISO XRD	J <sup>3</sup> ISO PLM %	MAS ISO PLM %
M68503-010	1960	NAD	NAD	NAD
M68503-009	1962	NAD	NAD	NAD
M68508-024	1963	NAD	NAD	NAD
M68503-004	1964	NAD	NAD	NAD
M68503-014	1965	NAD	NAD	<0.1 Trem/Act

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M68503-011	1966	NAD	NAD	NAD
M68503-027	1966	NAD	NAD	NAD
M69042-007	1966-1967	NAD	---	NAD
M69042-003	1967	NAD	---	<0.1 Trem/Act <0.1 Anth
M69042-005	1967	NAD	---	NAD
M69042-006	1967	NAD	---	NAD
M68503-019	1967	NAD	NAD	NAD
M68503-038	1968	NAD	NAD	NAD
M68503-026	1969	NAD	NAD	<0.1 Trem/Act

NAD: no asbestos detected

### Summary of J<sup>3</sup> XRD & J<sup>3</sup>/ MAS PLM Analysis

#### 1970's

MAS Sample Number	Date of Manuf.	ISO XRD	J3 ISO PLM %	MAS ISO PLM %
M68503-005	1970	NAD	NAD	NAD
M69042-009	1970	NAD	---	<0.1 Trem/Act
M68503-029	1971	NAD	NAD	NAD
M68503-021	1972	NAD	NAD	NAD
M68503-023	1973	NAD	NAD	<0.1 Anth.
M68503-028	1974	NAD	NAD	NAD
02D	1975	NAD	NAD	---
M69042-001	1975	NAD	---	<0.1 Trem/Ac <0.1 Anth
M68503-046	1975	NAD	NAD	NAD
M68503-042	1976	NAD	NAD	<0.1 Trem/Act <0.1 Anth
M68233-001	1978	NAD	—	<0.1 Trem/Act <0.1 Anth



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M68233-002	1978	NAD	—	<0.1 Trem/Act <0.1 Anth
M68503-057	1978	NAD	NAD	<0.1 Trem/Act <0.1 Anth
M68503-020	1978	NAD	NAD	<0.1 Anth
M69042-002	1978	NAD	---	<0.1 Trem/Act <0.1 Anth
M69042-004	1978	NAD	—	<0.1 Trem/Act <0.1 Anth
M69042-008	1978	NAD	---	<0.1 Anth
07D	1978	NAD	NAD	--
15D	1978	NAD	NAD	--
50D	1978	NAD	NAD	--
M68503-059	1979	NAD	NAD	<0.1 Trem/Act <0.1 Anth

NAD: no asbestos detected \*: not analyzed

### Summary of J<sup>3</sup> XRD & PLM Analysis

#### 1980's

MAS/P <sup>3</sup> Sample Number	Date of Manuf.	ISO XRD	J3 ISO PLM	MAS ISO PLM
10D	1980	NAD	NAD	--*
38D	1980	NAD	NAD	--
63D	1980-1981	NAD	NAD	--
52D	1981	NAD	NAD	--
65D	1981	NAD	NAD	--
37D	1982	NAD	NAD	--
45D	1982	NAD	NAD	--
51D	1982	NAD	NAD	--
66D	1982	NAD	NAD	--
21D	1983	NAD	NAD	--
M68503-001	1984	NAD	NAD	<0.1% Trem/Act
M69042-010	1985	NAD	---	<0.1% Trem/Act
31F	1986	NAD	NAD	--